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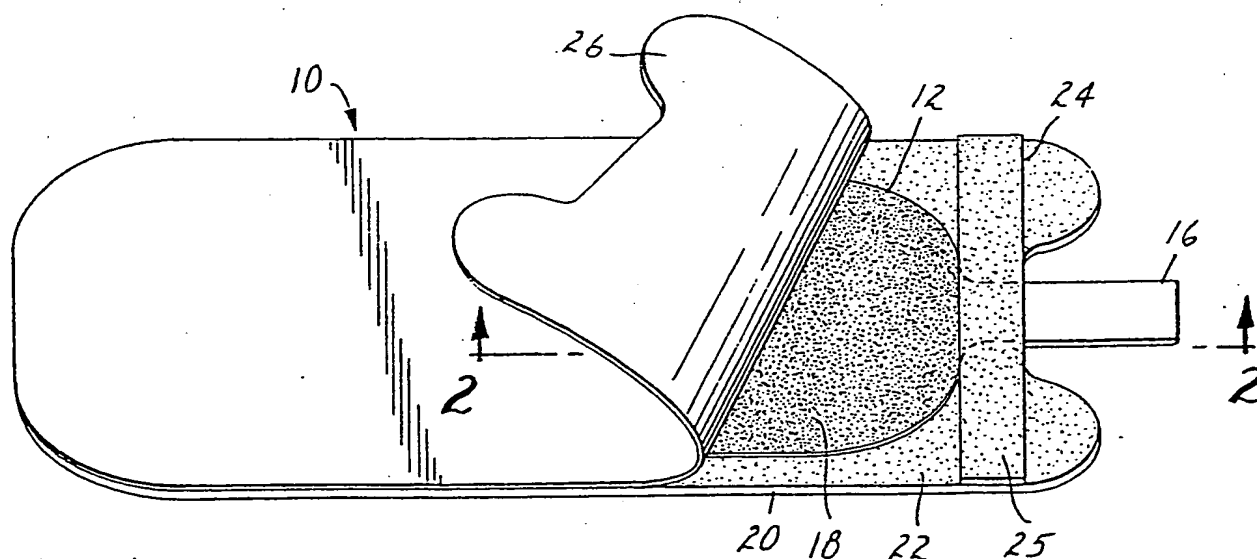
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(54) Title: CONDUCTIVE ADHESIVE AND BIOMEDICAL ELECTRODE



## (57) Abstract

A biomedical electrode (10, 30) having a conductive adhesive (18, 36) thereon which is derived from an essentially solventless process. The resulting adhesive is characterized in that it is a swellable, dermally-nonirritating, conformable, cohesive, ionic, hydrophilic polymer.

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CONDUCTIVE ADHESIVE AND  
BIOMEDICAL ELECTRODE

This invention relates to a conductive adhesive especially useful in biomedical electrodes used to establish an electrical connection between the skin of the human anatomy and an electromedical apparatus, such as a high impedance electromyograph, electrocardiograph, electrical neurostimulator for pain relief, and the like. More particularly it relates to a conductive adhesive for use in so-called "dry" bioelectrodes which do not require the use of messy creams or gels to enhance conductivity between the skin and the electrode plate.

A variety of disposable biomedical electrodes are known in the art. Generally, they comprise a metallic electrode plate adapted for connection to a lead wire which is, in turn, attached to the electromedical apparatus. Typically, a paste, cream, or gel which contains ionic material is relied upon to conduct the electric current and improve the electrical connection between the skin of the patient and the electrode plate. An adhesive tape is commonly used to adhere the entire apparatus to the skin. Examples of electrodes of this general type are described in U.S. Patents 3,587,565 and 3,805,769.

The conductive pastes, creams, or gels used in these prior art biomedical electrodes are unpleasant to use, sloppy, and often irritating to the skin particularly when the skin is cleaned and abraded prior to application of the electrode. Since these electrodes all contain water as the major ingredient to solvate the ions present and function as a medium through which the solvated ions migrate, they require elaborate packaging to prevent loss of water prior to use. Furthermore, they leave a residue on the skin after removal of the electrode which requires



cleanup. A further disadvantage of the electrodes of the conductive paste, cream, and gel types is that they may develop an overpotential in defibrillation procedures unless the surface of the electrode plate is of expensive silver/silver chloride.

To overcome many of the problems associated with so called "wet" electrodes, biomedical electrodes having an integrally formed metal snap connector have been proposed which utilize "dry" conductive material. U.S. Patents 4,008,721 and 3,911,906 disclose biomedical electrodes utilizing adhesives impregnated with conductive particles. These adhesives serve the dual purpose of enhancing conductivity with the skin and securing the electrode to the skin. Although avoiding the sloppiness and packaging problems associated with gels and pastes, such electrodes generally do not provide satisfactory electrical connection to the skin because the presence of the conductive filler results in a high signal-to-noise ratio and is deleterious to adhesion. Generally, the use of nonhomogeneous conductive formulations in bioelectrodes has been found to give rise to noisy electrical signals. It is speculated that dispersed metal or salt particles in a binder matrix form a discontinuous, electrically conductive path which develops random, nonuniform electrical fields between particles which cause noise.

Another biomedical electrode used for transcutaneous electrical neural stimulation (TENS) disclosed in U.S. Patent No. 4,125,110 utilizes a natural polymer, namely, gum karaya, for securing the electrode to skin. Gum karaya is a complex polysaccharide combined with certain metallic cations, such as sodium, potassium, calcium, or magnesium. The gum does not dissolve but swells in water to a paste-like gel (Kirk-Othmer, Encyclopedia of Chemical Technology, Vol. 10, 1966). Because natural polymers originate in nature where soil and climatic conditions are variable, and the conditions under which they are collected and processed are variable,



processing of the conductive layer of the present invention the precursor may also contain at least one non-ionic unsaturated free radically polymerizable comonomer which is soluble in the polyhydric alcohol.

5           The term "solventless" is used herein to mean that there are essentially no materials present in the precursor which are not present in the final composition of the electrically conductive adhesive. Stated another way, when the polymerization of the precursor is complete  
10 and the adhesive is ready for use at least 99% of the starting materials are still present.

          The term hydrophilic is used herein to mean the conductive adhesive will absorb some water.

          The term "conformable" as used herein refers  
15 generally to the compliance of the conductive material. It must be sufficiently compliant to conform to the surface of the skin beneath the electrode plate to provide a high surface area of contact between the skin and the electrode plate.

20           The term "cohesive" refers to the internal integrity of the conductive material. Generally, the conductive material is film-forming and must be more cohesive than adhesive to the skin so that, when the electrode is removed from the skin, the conductive layer  
25 remains intact and does not leave an objectionable residue.

          The term "swellable" refers to the imbibing of solvents by the polymer matrix with a concomitant increase in the volume of the polymer matrix.

30           The electrically conductive material is derived from the essentially solventless process of polymerizing the precursor of which one component is the water-soluble polyhydric alcohol. The polyhydric alcohol is water soluble and a liquid at room temperature, e.g.  
35 approximately 20°C. The polyhydric alcohol is present in the precursor in amounts of from 10 to 90 parts per weight of the precursor, with 50 to about 70 being preferred.



Examples of useful polyhydric alcohols are propylene glycol, 1,2,4 Butane triol and glycerol, with the latter being preferred. One skilled in the art will recognize that a mixture may be prepared of polyhydric alcohols  
5 which are not normally liquid at room temperature and those that are liquid to form a useful polyol. One skilled in the art would also recognize that the dihydric alcohol, ethylene glycol may be useful in the present invention but may cause dermal reactions which limit their  
10 utility.

As stated above, the precursor is also comprised of the unsaturated free radically polymerizable material which is soluble in the polyhydric alcohol. This material may be a monomer or comonomer. These monomers or  
15 comonomers are present in the precursor in amounts of 90 to 10 parts by weight of the precursor. Of the amount of unsaturated monomer or comonomers which are present in the precursor at least 10 parts by weight is ionic. This ionic portion is preferably anionic and present in 30  
20 parts by weight of the unsaturated monomer or comonomer. Examples of ionic comonomers are salts of , -unsaturated carboxylic acids such as potassium acrylate or sodium methacrylate. Examples of useful non-ionic comonomers of  
25 free radically polymerizable monomers which are soluble in the polyhydric alcohol are acrylic acid, methacrylic acid and hydroxyethyl methacrylate.

The precursor is further comprised of 0.1 to 5 parts by weight per 100 parts of the unsaturated material of a crosslinking agent of a multifunctional unsaturated  
30 free radically polymerizable material. Examples are triethyleneglycol-bis-methacrylate, ethyleneglycol-bis-methacrylate, bisacrylamide, and triethyleneglycol-bis-acrylate with the former being preferred in amounts about 0.75 to about 1.5 part.

35 The initiation of the polymerization within the precursor is facilitated by the presence of at least 0.1 part by weight per 100 parts of the unsaturated material



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of a free radical initiator which is soluble in the polyhydric alcohol. The initiator may be of the thermal or photo class. The actual selection is dependent on the monomers and the polyhydric alcohol. An example of useful thermal initiators are benzoyl peroxide, azobisisobutyronitrile Di-t-butyl peroxide and Cumyl peroxide. Examples of useful photoinitiators are disclosed in the article Photoinitiators - An Overview by G. Berner et al in the Journal of Radiation Curing (April 1979), pp. 2 through 9. The preferred photoinitiator is benzeldimethylketal.

It will be recognized by one skilled in the art that other additives (e.g. tackifiers, such as polyacrylic acid) may be added to the precursor without departing from the spirit of the invention.

The essentially solventless precursor can be coated on to the electrode plate or transfer sheet and depending on the free radical initiator exposed to either heat or actinic radiation which results in the formation of an electrically conductive pressure-sensitive adhesive. The precursor may also be exposed to electron beam radiation to facilitate the crosslinking.

A better understanding of the present invention will be obtained with reference to the following drawing wherein like numbers refer to like parts and in which:

FIGURE 1 is a perspective view of a grounding plate biomedical electrode of the present invention;

FIGURE 2 is a sectional view of the biomedical electrode of the present invention through line 2-2 of

FIGURE 1;

FIGURE 3 is a perspective view of a TENS biomedical electrode of the present invention; and

FIGURE 4 is a sectional view of the alternative embodiment of the biomedical electrode of FIGURE 3 through line 4-4.

Referring to FIGURES 1 and 2 a grounding plate electrode 10 is depicted. The electrode is comprised of



an electrode plate 12 having a first surface and a second skin contacting surface and is constructed from an electrically conductive material such as stainless steel, silver, nickel or the like, compressed carbon or graphite, or a metal coated plastic, fabric, or conductive plastic material. The preferred material for use as electrode plate 12 is aluminum. When aluminum is utilized, it is preferred that the first surface is coated with a polyester backing 13 to facilitate handling. The electrode plate has means associated therewith for electrical connection to a lead wire which is in turn connected to an electromedical device. In electrode 10 the means for electrical connection to a lead wire is illustrated by connector tab 16. Connector tab 16 may be adapted to fit an electromedical connecting clip which is well known to the medical art, e.g., U.S. Patent 4,061,408 or equipped with a permanent lead wire (not shown). The skin contacting surface of the electrode plate, i.e., second surface, is coated with a layer 18 of conductive material to be described below. Layer 18 is generally between about 5 to about 100 mils (0.12 mm to 2.54 mm) thick with approximately 10 mil (0.25 mm) being preferred. Overlying the polyester backing 13 and extending outward from the periphery thereof is a backing 20. Backing 20 aids in holding the electrode securely to the skin of the patient. Backing 20 is preferably made of a closed cell foam with an adhesive coating 22. The backing may be constructed from a vinyl foam tape sold as "Microfoam" brand surgical tape by 3M Company, St. Paul, Minnesota. Another is a closed cell polyethylene foam, sold as "Volara" brand foam by the Voltex Corporation of Lawrence, Massachusetts. The adhesive 22 may be of the type disclosed in U.S. Patent 2,973,286. An insulating strip 24 of polyethylene may be added if it is believed that the connector tab 16 is in need of additional insulation at the portion nearest the means external electrical connection. Optionally, insulating strip 24 may have a double sided adhesive





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coating 25 of material similar to that of adhesive layer 22 which would allow strip 24 to aid in the securing of the electrode to the patient. An optional release liner 26 may be attached to the adhesive coated surfaces of the electrode 10 in order to preserve the adhesive character until ready for use. Such release liners are well known to the art.

The present invention contemplates the use of the novel solventless process for construction of an alternative biomedical electrode construction similar to that disclosed in U.S. Patent Application Serial No. 64,576 filed by Frank C. Larimore on August 7, 1979, which is a continuation-in-part of his United States Patent Application Serial No. 22,469, filed March 21, 1979. As shown in FIGURES 3 and 4, alternative biomedical electrode 30 (a TENS electrode) is comprised of an electrode plate 32 of a carbon-impregnated silicone rubber, i.e., SE 7600 available from the General Electric Company, Waterford, New York. In electrode 30 the means for electrical connection to a lead wire is illustrated by female receptor 34. Female receptor 34 is adapted to fit a male pin lead of a connector. The second skin contacting surface of electrode plate 32 is positioned onto a layer 36 of conductive material, described hereinabove, which had previously been formed on a transfer surface. In contrast to biomedical electrode 10, the layer 36 extends out to the outer periphery of a backing 38. Layer 36 is generally between 25 and 100 mils (0.63 mm and 2.54 mm). The electrode 30 is also optionally provided with a protective release liner 40. Release liner 40 protects the conductive layer from contamination prior to use.

A better understanding of the process of the present invention may be obtained from the following non-limiting examples:



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Example IPreparation of adhesive precursor.

Triethyleneglycol-bis-methacrylate (0.1g) and 0.1 gram of Irgacure 651 (a benzildimethylketal produced by Ciba-Geigy) were dissolved in 25 grams of acrylic acid. This solution was added to 50 grams of glycerol. The mixture was stirred and a solution of 7 grams of potassium hydroxide in water (10ml) was added. The resulting warm solution was cooled to room temperature before being used for coating.

The cooled adhesive precursor was knife coated onto an aluminum substrate consisting of a 1/2 mil. aluminum foil which had been laminated to a 1/2 mil. polyester backing. The resulting coating thickness was 6.7 mils (0.17 mm).

The coated substrate was then passed through a 3 foot inert chamber (N<sub>2</sub> atmosphere) under a bank of UV lights consisting of thirty 18-inch "black light" tubes for one minute which resulted in the polymerization of the coating. One-inch strips of the aluminum-laminate with polymerized coating were allowed to equilibrate for one week at 5%, 50% and 80% relative humidity (R.H.) and 74°F. 5% R.H. was obtained by storing the sample in a bell jar over Drierite (Na<sub>2</sub>SO<sub>4</sub> sold by W. A. Hammond Drierite Co. of Xenia, Ohio) 50% R.H. was obtained by storing in a room with controlled humidity. 80% R.H. was obtained by storing the samples in a bell jar over saturated (NH<sub>4</sub>)<sub>2</sub>SO<sub>4</sub>. After equilibrating for one week the samples were tested for conductivity. The impedance (Z) in Ohms ( ) to steel and phase angle ( ) were measured using a two square inch piece of stainless steel and a HP 4800 beta impedance meter (manufactured by Hewlett Packard of Palo Alto, Calif.) with the frequency set at 500 KHz. The adhesion to steel (180° peel) in ounces per inch (oz/in) were obtained by placing a one inch wide strip of adhesive on a stainless steel plate. The strip was then rolled twice with a 2 1/2 lb. roller. The force required to peel



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off the adhesive at 180° angle was measured using a Model #1122 Instron<sup>®</sup>, manufactured by the Instron Corporation of Canton, Massachusetts.

The results were:

5	Impedence		Adhesion to Steel	
	% R.H.	$Z(\Omega)$	<u>(oz/in)</u>	
	5%	21	5	no transfer of adhesive observed
	50%	1.6	4.5	no transfer
10	80%	1.4	4.5	transfer

#### Examples II through XII

Examples II through XII were produced in accordance with the procedure of Example I except the amounts of the components were varied. The amount of each component used and test results obtained are tabulated below.

#### Example II

20	Triethyleneglycol-bis-methacrylate	0.26 g
	Ingacure 651 (benzildimethylketal)	0.19 g
	Acrylic Acid	37.5 g
	Glycerin	62.5 g
	Water	12.4 g
	KOH	12.4 g
	coating thickness	3.2 mils (0.08 mm)

25	Impedence		Adhesion to Steel	
	% R.H.	$Z(\Omega)$	<u>(oz/in)</u>	
	5%	6.4	10	no transfer
	50%	1.5	4	no transfer
	80%	1.4	3	slight transfer



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Example III

Triethyleneglycol-bis-methacrylate	0.35 g
Irgacure 651 (benzildimethylketal)	0.35 g
Acrylic Acid	70.0 g
Glycerin	130.0 g
Water	19.0 g
KOH	19.0 g
coating thickness	3.3 mils (0.08 mm)

% R.H.	Impedence	Adhesion to Steel
	Z (Ω)	(oz/in)
5%	8.6	5.5 no transfer
50%	2.0	4.0 no transfer
80%	1.1	3.5 transfer

Example IV same adhesive precursor as Example III,  
different coating thickness, coating thickness 13.2 mils  
(0.33 mm):

% R.H.	Impedence	Adhesion to Steel
	Z (Ω)	(oz/in)
5%	120	9 no transfer
50%	7.8	5 no transfer
80%	1.9	5 slight transfer

Example V

Triethylene glycol-bis-methacrylate	0.20 g
Irgacure 651 (benzildimethylketal)	0.20 g
Acrylic Acid	40.0 g
Glycerin	60.0 g
Water	10.9 g
KOH	10.9 g
coating thickness	9.3 mils (0.24 mm)



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	Impedence	Adhesion to Steel
<u>% R.H.</u>	<u>Z(<math>\Omega</math>)</u>	<u>(oz/in)</u>
5%	90	9 no transfer
50%	4.1	2 no transfer
5 80%	1.9	5.5 no transfer

Example VI

	Triethyleneglycol-bis-methacrylate	0.18 g
	Irgacure 651 (benzildimethylketal)	0.1 g
	Acrylic Acid	23.5 g
10	Glycerin	50.0 g
	Water	7 g
	KOH	7 g
	coating thickness	11.0 mils (0.28 mm)

	Impedence	Adhesion to Steel
<u>% R.H.</u>	<u>Z(<math>\Omega</math>)</u>	<u>(oz/in)</u>
15 5%	NOT TESTED	
50%	6.4	2.5 no transfer
80%	NOT TESTED	

Example VII

20	Triethyleneglycol-bis-methacrylate	0.18 g
	Irgacure 651 (benzildimethylketal)	0.18 g
	Acrylic Acid	35.0 g
	Glycerin	65.0 g
	Water	13.6 g
25	KOH	13.6 g
	coating thickness	11.1 mils (0.28 mm)

	Impedence	Adhesion to Steel
<u>% R.H.</u>	<u>Z(<math>\Omega</math>)</u>	<u>(oz/in)</u>
5%	6.4	14 no transfer
30 50%	1.9	5 no transfer
80%	1.2	4.5 no transfer



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Example VIII

	Triethyleneglycol-bis-methacrylate	0.04 g
	Irgacure 651 (benzildimethylketal)	0.18 g
	Acrylic Acid	35.0 g
5	Glycerin	65.0 g
	Water	9.5 g
	KOH	9.5 g
	coating thickness	9.2 mils (0.23 mm)

		Impedence	Adhesion to Steel
10	<u>% R.H.</u>	<u>Z (Ω)</u>	<u>(oz/in)</u>
	5%	66	10 no transfer
	50%	3.7	4.5 no transfer
	80%	1.6	11 excessive transfer

15 From Examples I through VIII, it can be seen that by varying the components of the precursor the conductivity cohesive properties may be adjusted to suit the humidity condition under which the conductive adhesive will be used. In the observation of the adhesion to steel

20 the term transfer was used herein to mean slight adhesive residue was observed. It should be noted that it has been observed by the applicant that the composition that exhibited some transfer when tested on steel did not leave adhesive residue on human skin. The useful conductivity

25 level is largely dependent on the type electrode on which the final polymer is applied. For example, in a ground plate electrode the conductivity is preferably less than 30 ohms at 50% (R.H.).

Example IX30 Preparation of Adhesive Precursor.

Triethyleneglycol-bis-methacrylate (0.1 g) was dissolved in hydroxyethylmethacrylate (10 g) and added to 50 grams of glycerol. The mixture was stirred and a solution of 0.1 gram benzildimethylketal dissolved in 15

35 grams of acrylic acid was added and mixed. A solution of



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potassium hydroxide (6.0 g) and water (10 ml) was then added. All components were combined within 10-15 minutes and then placed in a dark refrigerator to prevent premature polymerization. Test strips were then prepared in accordance with procedures outlined in Example I. A 11 mil (0.28 mm) thick layer of polymer at 50° relative humidity the polymer exhibited a Z of 7.2 ohms and an adhesion of 1 oz/in.

#### Example X

##### Preparation of Adhesive Precursor.

Triethyleneglycol-bis-methacrylate (0.1 g) and 0.1 gram benzildimethylketal were dissolved in 32.5 grams of acrylic acid. This solution was rapidly added to 50 grams of glycerin. The mixture was stirred thoroughly and a solution of sodium hydroxide (5.0 g) and water (30 ml) was then added. All components were combined within 10-15 minutes and then placed in a dark refrigerator to prevent premature polymerization.

After the cooling of the precursor test strips were prepared and tested as outlined in Example I. A test strip having a 11 mil (0.28 mm) thick polymer layer at 50% relative humidity exhibited a Z of 9 ohms, and an adhesion of 8.5 oz/in.

#### Example XI

##### Preparation of Adhesive Precursor.

Triethyleneglycol-bis methacrylate (0.1 g) and benzildimethylketal (0.1 g) were dissolved in 23.5 grams of acrylic acid. This solution was rapidly added to 50 grams of Sutro 970 (a mixture of polyols sold by ICI United States Inc. of Wilmington, Delaware). The mixture was stirred thoroughly and a solution of potassium hydroxide (6 g) and water (10 g) was added. All components were combined within 10 to 15 minutes and then placed in a dark refrigerator.



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After the cooling of the precursor, test strips were prepared and tested as outlined in Example I. A test sample having a 11 mil (0.28 mm) thick polymer layer at 50% relative humidity, exhibited a Z 200 ohms, and an  
5 adhesion of 1.5.





What Is Claimed Is:

1. In an essentially dry biomedical electrode comprising an electrode plate having a first surface and a second surface, said electrode plate having means for  
5 electrical connection to a lead wire of an electro-medical device, and a conductive material on said second surface of said electrode plate for enhancing electrical connection with the skin, the improvement wherein said conductive material comprises a swellable,  
10 dermally-nonirritating, conformable, cohesive, ionic, hydrophilic polymer formed by the essentially solventless process of:

- (a) compounding an adhesive precursor comprising
  - (1) a water-soluble polyhydric alcohol which is  
15 a liquid at about 20°C;
  - (2) an ionic unsaturated free radically polymerizable material which is soluble in said polyhydric alcohol;
  - (3) a free radical initiator; and
  - 20 (4) a crosslinking agent of a multifunctional unsaturated free radically polymerizable material;
- (b) coating said adhesive precursor on said second surface of said electrode plate; and
- (c) polymerizing said coated precursor whereby an  
25 electrically conductive pressure-sensitive adhesive is formed on said electrode plate.

2. In an essentially dry biomedical electrode comprising an electrode plate having a first surface and a second surface, said electrode plate having means for  
30 electrical connection to a lead wire of an electro-medical device, and a conductive material on said second surface of said electrode plate for enhancing electrical connection with the skin, the improvement wherein said conductive material comprises a swellable,  
35 dermally-nonirritating, conformable, cohesive, ionic, hydrophilic polymer formed by the essentially solventless



process of:

- (a) compounding an adhesive precursor comprising
- (1) a water-soluble polyhydric alcohol which is a liquid at about 20°C;
  - 5 (2) an ionic unsaturated free radically polymerizable material which is soluble in said polyhydric alcohol;
  - (3) a free radical initiator; and
  - (4) a crosslinking agent of a multifunctional
  - 10 unsaturated free radically polymerizable material;
  - (b) coating said adhesive precursor onto a releasable transfer surface;
  - (c) polymerizing said coated precursor whereby an electrically conductive pressure-sensitive adhesive is
  - 15 formed on said releasable transfer surface; and
  - (d) adhering said polymerized electrically conductive adhesive to the second surface of said electrical plate.

3. The essentially dry biomedical electrode of

20 claims 1 or 2 wherein the precursor is further comprised of at least one non-ionic unsaturated free radically polymerizable monomer or comonomer which is soluble in the polyhydric alcohol.

4. The essentially dry biomedical electrode

25 according to claims 1 or 2 wherein said polyhydric alcohol comprises from about 10 to about 90 parts per weight of said precursor.

5. The essentially dry biomedical electrode

according to claim 4 wherein said polyhydric alcohol is

30 glycerol.



6. The essentially dry biomedical electrode according to claims 1 or 2 wherein said precursor is comprised of at least 1 part by weight of said ionic unsaturated free radically polymerizable material.

5           7. The essentially dry biomedical electrode according to claim 6 wherein said ionic material is potassium acrylate.

8. The essentially dry biomedical electrode according to claims 1 or 2 wherein the free radical  
10 initiator is a photoinitiator.

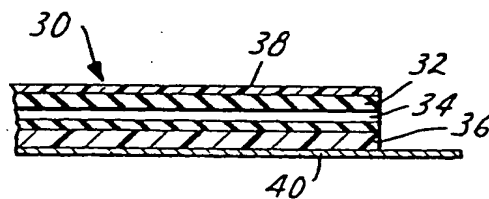
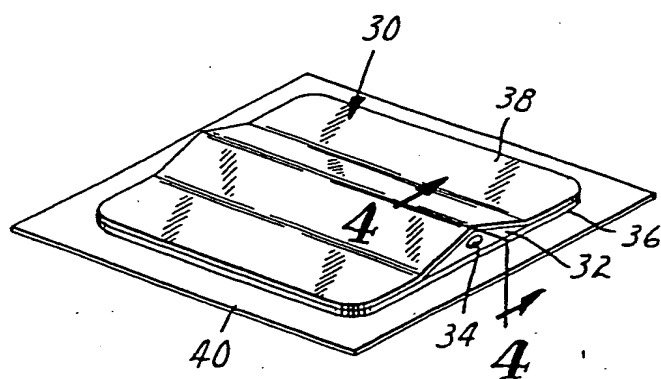
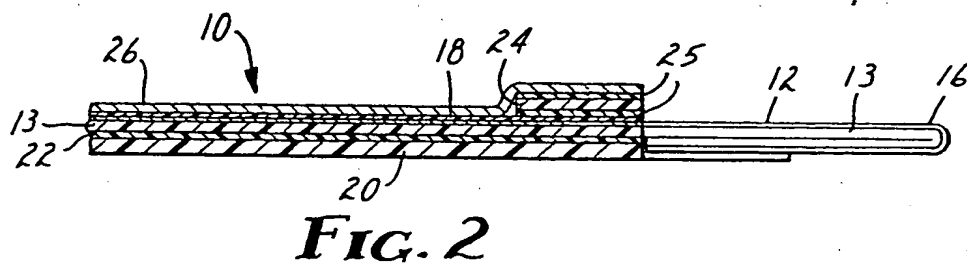
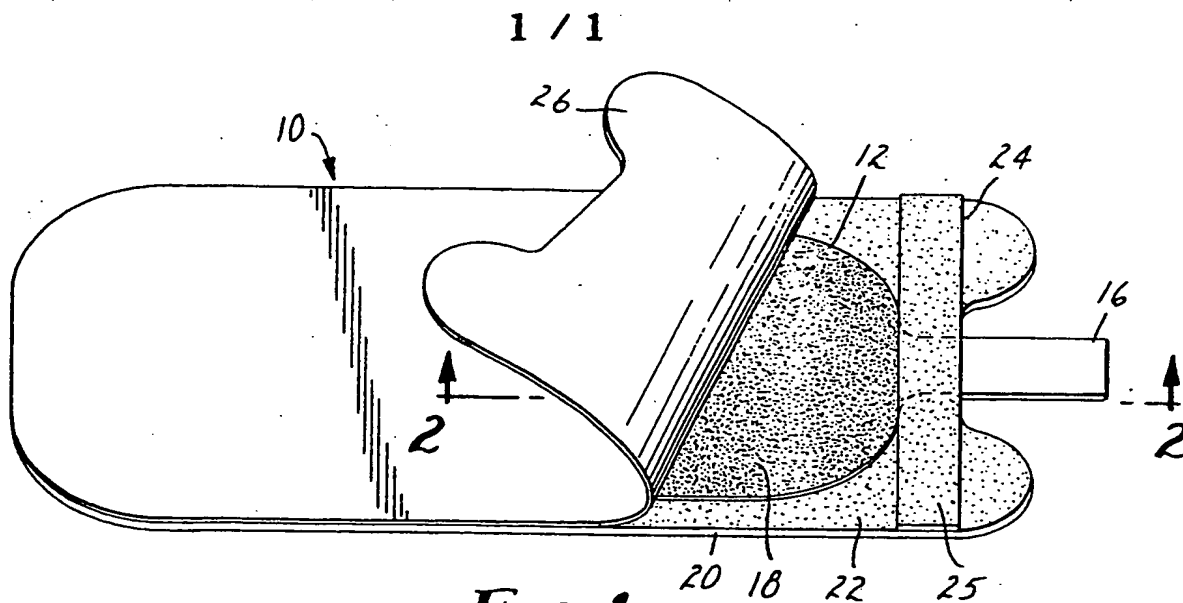
9. The essentially dry biomedical electrode according to claim 8 wherein the free radical initiator is benzildimethylketal.

10. An essentially dry biomedical electrode  
15 comprising an electrode plate having a first surface and a second surface, said electrode plate having a means for electrical connection to a lead wire of an electro-medical device, and a conductive material on said second surface of said electrode plate for enhancing electrical  
20 connection with the skin, said conductive material being a swellable, non-soluble, dermally-nonirritating, conformable, cohesive, ionic, hydrophilic polymer derived from the essentially solventless in situ polymerization of a water-soluble polyhydric alcohol which is a liquid at  
25 about 20°C and an ionic unsaturated free radically polymerizable material which is soluble in said polyhydric alcohol in the presence of a crosslinking agent of a multifunctional unsaturated free radically polymerizable material and a free radical initiator.



11. An electrically conductive swellable, non-soluble, dermally-nonirritating, conformable, cohesive, ionic hydrophilic adhesive derived from an essentially solventless polymerization of a precursor  
5 comprised of a water-soluble polyhydric alcohol which is a liquid at about 20°C, an ionic unsaturated free radically polymerizable material which is soluble in said polyhydric alcohol, a crosslinking agent of a multifunctional unsaturated free radically polymerizable material and a  
10 free radical initiator soluble in said polyhydric alcohol, said polymerized precursor resulting in an adhesive which is characterized in that it is a conductive polymer.





# INTERNATIONAL SEARCH REPORT

International Application No PCT/US80/01543

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
INT. CL. 3 A61B 5/04; A61N 1/04		
U.S. CL. 128/640; 128/798		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched *		
Classification System	Classification Symbols	
U.S.	128/639-641, 644, 303.13, 783, 798, 802, 803	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> 14		
Category *	Citation of Document, 15 with indication, where appropriate, of the relevant passages 17	Relevant to Claim No. 18
X	US, A, 4,066,078, Published 03 January 1978, Berg.	1-11
X	US, A, 4,125,110, Published 14 November 1978, Hymes.	1-11
A	US, A, 3,587,565, Published 28 June 1971, Tatoian.	1,2,10
A	US, A, 3,805,769, Published 23 April 1974, Sessions.	1,2,10
A	US, A, 3,812,861, Published 28 May 1974, Peters.	1,2,10
A	US, A, 3,911,906, Published 14 October 1975, Reinhold, Jr.	1-11
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<p>* Special categories of cited documents: 15</p> <p>"A" document defining the general state of the art</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document cited for special reason other than those referred to in the other categories</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but on or after the priority date claimed</p> <p>"T" later document published on or after the international filing date or priority date and not in conflict with the application, but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search *	Date of Mailing of this International Search Report *	
04 May 1981	14 MAY 1981	
International Searching Authority *	Signature of Authorized Officer 19	
ISA/US	Lee S. Cohen	

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